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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,037	09/17/2003	Richard D. Guarino	P-6186	2610

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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/664,037	Applicant(s) GUARINO ET AL.	
	Examiner Vera Afremova	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 58-61 is/are pending in the application.
- 4a) Of the above claim(s) 9,11,59 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,10,12-16,58 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/09/05; 7/15/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (original claims 1-16) in the reply filed on 12/21/2006 is acknowledged. The traversal is on the ground(s) that the original claims encompass variants of the same invention(s). However, applicants' arguments are moot due to cancellation of original claims 17-57. Thus, the requirement is still deemed proper and is therefore made FINAL.

In response to election of species requirement applicants elected the following combination: collagen type I (ECM material), hyaluronic acid (CAR material) and poly-L-ornithine (active factor) as readable in claims 1-8, 10, 12-16 and 58 (response page 8).

Thus, original claims 9, 11 and new claims 59 and 60 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being nonelected. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/21/2006.

Claims 1-8, 10, 12-16, 58 and 61 are under examination in the instant office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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1. Claims 1-4, 7, 8 and 2-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/56897.

Claims are directed to a method for attaching and/or maintaining primary liver cells wherein the method comprising (a) providing a polymer composition comprising a cell adhesion resistant (CAR) material and ECM proteins bound to the CAR material in order to form a cell adhesion promoting surface; and (b) incubating the liver cells in the presence of the surface and a culture medium wherein the liver cells attach to the surface and are maintained in a functional state. Some claims are further drawn to the use of the ECM proteins such as collagen type I and to the CAR material such as hyaluronic acid (HA). Some claims are further drawn to the use of 3D scaffold formed by ECM proteins and to the use of flexible material in the surface polymer composition.

WO 98/56897 discloses a method for attaching and maintaining primary porcine liver cells in a functional state (page 13, example 6) by incubating the liver cells in a culture medium on a nonwoven HYAFF in co-culture with dermal fibroblasts that are seeded on the nonwoven HYAFF. The HYAFF matrices are made from hyaluronic acid (paragraph bridging pages 1 and 2). ECM proteins including collagen type I are provided by dermal fibroblasts. The dermal fibroblast ECM proteins provide for 3D scaffold for liver cells. The liver cell culture is maintained in plastic 24-well dishes that are made from plastic or generic flexible material within the broadest meaning of the claims. Thus, the cited method comprises identical active steps and identical structural elements as required by the claimed method. Therefore, the cited reference anticipates the claimed invention.

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2. Claims 1-3, 7, 8, 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,562,616 (Toner et al).

Claims are directed to a method for attaching and/or maintaining primary liver cells wherein the method comprising (a) providing a polymer composition comprising a cell adhesion resistant (CAR) material and ECM proteins bound to the CAR material in order to form a cell adhesion promoting surface; and (b) incubating the liver cells in the presence of the surface and a culture medium wherein the liver cells attach to the surface and are maintained in a functional state. Some claims are further drawn to the use of the ECM proteins such as collagen type I. Some claims are further drawn to the use of 3D scaffold formed by ECM proteins and to the use of flexible material in the surface polymer composition such as PDMS.

US 6,562,616 (Toner et al) discloses a method for attaching and/or maintaining primary porcine liver cells (col. 24, lines 52-63) wherein the method comprising incubating the liver cells on collagen type I coated glass slides (generic CAR material). The ECM proteins such as collagen type I provide liver cells for 3D scaffold within the meaning of the claims. US 6,562,616 also teaches the use of a flexible material such as PDMS for forming the surface composition in the method for culturing liver cells. Thus, the cited method comprises identical active steps and identical structural elements as required by the claimed method. Therefore, the cited reference anticipates the claimed invention.

3. Claims 1-4, 7, 8, 14, 15 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,942,436 (Dunn et al).

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Claims are directed to a method for attaching and/or maintaining primary liver cells wherein the method comprising (a) providing a polymer composition comprising a cell adhesion resistant (CAR) material and ECM proteins bound to the CAR material in order to form a cell adhesion promoting surface; and (b) incubating the liver cells in the presence of the surface and a culture medium wherein the liver cells attach to the surface and are maintained in a functional state. Some claims are further drawn to the use of the ECM proteins such as collagen type I. Some claims are further drawn to the use of 3D scaffold formed by ECM proteins and to the use of flexible material in the surface composition. Some claims are further drawn to the use of rat liver cells.

US 5,942,436 (Dunn et al) discloses a method for attaching and/or maintaining primary liver cells or rat hepatocytes in the presence of a surface composition comprising collagen type I (rat tail collagen) and plastic culture dish material that is generic CAR material and a generic flexible material. The culture system comprises a generic active factor such as EGF, for example. Thus, the cited method comprises identical active steps and identical structural elements as required by the claimed method. Therefore, the cited reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-8, 10, 12-16, 58 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/56897, US 6,562,616 (Toner et al) and US 5,942,436 (Dunn et al) taken with

The cited WO 98/56897, US 6,562,616 (Toner et al) and US 5,942,436 (Dunn et al) teach methods for incubating and/or maintaining mammalian liver cells attached to ECM proteins such as collagen type I that is coating or bound to non-adhesive (CAR) materials including HA. The cited references are lacking particular disclosure about the use of poly-L-ornithine in the surface coating composition in the method for culturing liver cells.

However, US 6,653,105 (Triglia et al) teaches methods for culturing mammalian liver cells including human hepatocytes (col. 4, line 6) and suggests the use of attachment surfaces that are composed of poly-ornithine and collagen as suitable compositions for attachment, incubating and growing hepatocytes (col. 6, lines 5-24). In addition, the cited JP 04322657 also teaches and/or suggests culturing liver cells in the presence of biologically active composition such as a mixture of materials selected from collagen, poly-L-ornithine, glasses, organic polymers and/or silicone-based rubbers (English abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to add poly-L-ornithine to the coating polymer compositions of WO 98/56897, US 6,562,616 (Toner et al) and/or US 5,942,436 (Dunn et al) with a reasonable expectation of success in culturing liver cells because the cell attachment surfaces comprising poly-L-ornithine and collagen type I have been taught and/or suggested by the prior art of attaching, incubating and growing hepatocytes as adequately demonstrated by the cited reference combined. The cited references are in the same field of endeavor and seek to solve the same

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problems as the instant application and claims, and one of skill in the art is free to select components available in the prior art, *In re Winslow*, 151 USPQ 48 (CCPA, 1966).

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

March 15, 2006



VERA AFREMOVA

PRIMARY EXAMINER